

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

Minnesota Pharmacists Association,
National Association of Chain Drug Stores,
National Community Pharmacists
Association, Minnesota Retailers
Association, Minnesota Grocers
Association, Astrup Drug, Inc., Coborn's,
Inc., Falk's Pharmacies, Inc., Genoa
Healthcare Minnesota, LLC, Goodrich
Pharmacy, Inc., JT Hoeschen, Inc. d.b.a.
St. Paul Corner Drug, Setzer Pharmacy, Inc.,
Thrifty Drug Stores, Inc., Trumm Drug,
Inc., Robert Diaz, and M.B., a minor, and
A.H., a minor, by and through their Legal
Guardian, James Brech,

Plaintiffs,

vs.

Timothy Pawlenty, not individually, but
solely in his official capacity as Governor of
the State of Minnesota, Cal Ludeman, not
individually, but solely in his official
capacity as Commissioner of the Minnesota
Department of Human Services, Brian
Osberg, not individually, but solely in his
official capacity as Director of the
Minnesota Medicaid Program, the
Minnesota Department of Human Services,

Defendants.

Civil File No. 09-CV-2723 (DWF/RLE)

**REPLY MEMORANDUM IN
SUPPORT OF DEFENDANTS'
MOTION TO FOR JUDGMENT
ON THE PLEADINGS**

INTRODUCTION

Defendants submit this memorandum in response to Plaintiffs' arguments opposing Defendants' Motion for Judgment on the Pleadings. Plaintiffs initially spend a

significant amount of time arguing the merits of their federal law claims.¹ They vigorously contend that Plaintiffs have standing to bring this action and have plead sufficient facts to establish their standing. Defendants disagree.

I. PLAINTIFFS FAILED TO PLEAD SUFFICIENT FACTS TO MAINTAIN THEIR ACTION.

Plaintiffs' complaint is devoid of facts that demonstrate they have standing to bring this action. Plaintiffs' speculation about the future consequences of the rate the Medicaid fee-for-service program has paid for single-source, brand-name drugs since October does not establish standing. *Benton v. Merrill Lynch & Co., Inc.* 524 F. 3d 866, 870 (8th Cir. 2008) (Plaintiff must allege facts raising more than speculative right to relief).

A. Pharmacy And Association Plaintiffs Have Failed To Establish Their Standing.

The Pharmacy and Association Plaintiffs complain about the reduction in payments that resulted from the one percent increase in the discount applied to the Average Wholesale Price (AWP) of single-source, brand-name drugs, and the rollback in fraudulently inflated AWP's.² Although their complaint sets out a litany of horrors that

¹ In arguing the merits of their claims Plaintiffs emphasize access and quality care and completely ignore the two other equally important criteria set out in Section 30(A)—economy and efficiency.

² Plaintiffs self-righteously assert that the only reason they brought this action is to ensure Minnesota's least fortunate will receive the access to prescription medications that federal law requires. Pl. Resp. Mem, 24, p. 1. Defendants suspect that the Association and Pharmacy Plaintiffs' motives are not quite so pure. Their professed motivation is belied by who is actually bringing this suit. The three Medicaid recipients plaintiffs have not experienced any access issues as plead in the complaint and appear to be simply repeating the providers' speculations.

they assert will come to pass, none of the adverse affects have actually occurred. Similarly the declarations Plaintiffs submitted, in support of their preliminary injunction motion, only speculate about the actions some pharmacies may take in the future. One lone declaration stated that a pharmacy provider will not participate in the program because of the rate paid. That declaration was submitted by a Costco executive who admitted that the company's pharmacies have never participated in Minnesota's and most other states' Medicaid programs. See Document 32, ¶¶5, 9. That is not evidence that the one percent reduction and the rollback have affected access.

Moreover Plaintiffs exaggerate the harm Minnesota pharmacies face. They contend that prices paid for thousands of drugs have been cut by five percent. Pl. Resp. Mem. p. 1. Although the one percent increase in the discount rate passed by the Minnesota Legislature and signed into law by the Governor affects Medicaid payments for all single-source, brand-name drugs, the majority of the drugs paid for by the program are generic drugs, not single-source, brand-name drugs. See Drake Aff. ¶ 24, Document 52. Moreover the 3.9 percent reduction that resulted from First DataBank's rollback of illegally inflated Average Wholesale Prices ("AWP") on September 26, 2009, affected only 6,450 drugs of the 25,000 drugs covered by Minnesota's Medicaid program. *Id.* ¶ 19. Many of the 6,450 affected drugs are rarely prescribed. The Medicaid fee-for-service program has been billed for only 2,045 (less than one-third) of the 6,450 drugs affected by the rollback since the beginning of the year. *Id.* Over 11 percent of the

affected drugs that were billed to Minnesota's Medicaid program have had their AWP's increased an average of 8.1 percent since the September 26th rollback. *Id.* 20.

Plaintiffs contend that harm is imminent. However, the one percent increase in the discount applied to AWP has been in effect since July 1, 2009. Pharmacy participation in the Medicaid fee-for-service program has not decreased since the one percent reduction in the rate paid for brand-name prescription drugs went into effect. *Id.* 13.

Plaintiffs are obviously more concerned about the reduction in AWP's that First DataBank implemented as part of a settlement of a federal multi-district fraud action. See *New England Carpenters Health Benefits Fund v. First DataBank, Inc.*, 602 F. Supp. 2d 277 (D. Mass. 2009). At least one of the Plaintiffs in this action, the National Association of Chain Drug Stores, along with other pharmacy groups, attempted to intervene in the federal multi-district action and objected to the rollback, predicting that it would drive pharmacies out of business. *Id.* at 283. The district court in approving the settlement rejected the pharmacy associations' dire predictions. The pharmacy groups then appealed to the First Circuit Court of Appeals again listing the adverse consequences that would result from the AWP rollbacks. *National Association of Chain Drug Stores v. New England Carpenters Health Benefits Fund*, 582 F. 3d 30 (1st Cir. 2009). The appellate court, like the district court, discredited their dire predictions and refused to grant the pharmacy groups the relief they sought. *Id.*

The pharmacy groups, after being unsuccessful in federal court, voiced their concerns to HHS Secretary Sebelius. See Berg Aff. ¶ 9 Ex. 4, Document 53. They asked the Secretary to require states to adjust their Medicaid payment rates in light of the AWP

rollback. Secretary Sebelius refused, noting that the prices of the affected drugs had been illegally inflated for over eight years and the pharmacies had benefited from the higher payments made by states and other third party payers. *Id.*

After failing to persuade two federal courts and the federal agency, the Pharmacy and Association Plaintiffs now ask this Court to order Minnesota to continue to pay pharmacies on the basis of the fraudulently inflated AWP, reciting the same list of potential consequences that failed to persuade the courts and federal agency. However, they have not shown one single pharmacy that has withdrawn from the program, cut services or quality as a result of the current payment rate. Their speculation is insufficient to state a cause of action. Cf. *K-2 Ski Co. v. Head Ski Co.*, 467 F. 2d 1087, 1088-89 (9th Cir. 1972) (Finding that complaint and affidavits consisting largely of contraverted general assertions do not support relief).

B. Recipient Plaintiffs Also Failed To Plead Sufficient Facts To Establish Standing.

Like the Pharmacy Plaintiffs, the Recipient Plaintiffs vague and meager factual statements in the complaint and in their declarations fail to set out sufficient facts to establish a cause of action against the Defendants. The Recipient Plaintiffs contend that they may be unable to obtain prescription drugs in the future because of the current Medicaid payment rate. They have not, however, stated that they are currently taking single-source, brand-name drugs which are paid at the challenged rate. Nor have they stated that a single pharmacy has refused to fill any prescription or informed them that it will not fill their prescriptions in the future. Recipient Plaintiffs have not plead sufficient

facts to show that they have been harmed or are likely to be harmed. Instead they state that they fear they may be denied access to pharmacies in the future because of the Medicaid payment rate. A vague fear of future harm, however, is insufficient to establish standing. See *Young America Corp. v. Affiliated Computer Services*, 424 F. 3d 840, 843 (8th Cir. 2005).

II. PLAINTIFFS' SUPREMACY CLAUSE CLAIM SHOULD BE DISMISSED.

Plaintiffs assert they have “standing”³ under the Supremacy Clause to bring this action. Pl. Resp. Mem. p. 10. They assert that Minnesota is not complying with section 30(A)’s equal access and quality of care requirements. Congress entrusted the task of determining whether a state’s Medicaid payment rates meet the requirements of section 30(A) to the Secretary of Health and Human Services. Section 30(A) is set out in 42 U.S.C. § 1396a(a). Section 1396a(a) lists the mandatory contents of state Medicaid plans. Congress has delegated to the Secretary of Health and Human Services the task of reviewing and approving state plans that meet the conditions set out in section 1396a(a). See 42 U.S.C. § 1396a(b). The federal agency has reviewed and approved Minnesota’s State Plan Amendment increasing to 15 percent the discount applied to the AWP’s of brand-name prescription drugs. See Berg Aff. ¶ 7, Ex. 3, Document 53. Moreover during its review of Minnesota’s amendment, the federal agency was aware that Minnesota was continuing to use the AWP’s published in First DataBank’s Blue Book,

³ Plaintiffs use of the term “standing” is incorrect. “Standing” should be limited to a particular individual’s case and controversy and prudential standing. Plaintiffs’ Supremacy Clause and §1983 issues are more appropriately considered as issues of whether a private right of action exists.

including the reduced AWP's affected by the rollback. *Id.* ¶ 5. The federal agency in approving the state plan amendment, concluded that the amendment set out a rate that was efficient and economical, and would provide recipients with quality pharmacy care and equal access to pharmacy services. The Secretary's decision on whether a state plan amendment complies with federal Medicaid requirements is entitled to considerable deference. *Pharmaceutical Research & Manufacturers of America v. Thompson*, 362 F.3d 817, 821 (D.C. Cir. 2004) (Secretary's approval of Medicaid State Plan Amendment entitled to *Chevron* deference); *in accord S.D. v. Hood*, 391 F.3d at 596; *Rosen v. Goetz*, 410 F.3d 919, 927 (6th Cir. 2005); *See also Dep't of Medical Assistance ex rel. Toal v. Shalala*, 8 F.3d 1565, 1572-73 (11th Cir. 1993) (applying *Chevron* deference to denial of state plan amendment). The Secretary found that Minnesota's payment rate complies with requirements of the Medicaid statute, including Section 30(A). Thus, there is no Supremacy Clause violation.

Courts that have found a Supremacy Clause violation faced a very different set of facts than the facts plead in this case. In *Independent Living Center v. Shewry*, 543 F.3d 1050, the Ninth Circuit Court of Appeals found that California's 10 percent reduction in Medicaid payments to numerous medical providers violated section 30(A) and therefore was preempted by the Supremacy Clause. When the court issued its decision, the Centers for Medicare and Medicaid Services had not approved California's reduction in provider payment rates. In addition the level of participation by California medical providers in the state's Medicaid program was much lower than the level of pharmacy participation in Minnesota's program. Less than 55 percent of California doctors and only 10 percent of

California dentists participated in the state program prior to the 10 percent reduction taking effect. *Id.* at 1053. By contrast the federal agency has approved Minnesota State Plan Amendment and 97 percent of Minnesota Pharmacies participate in the Medical program even after the payment rate has changed. See Drake Aff. ¶ 13, Document 52.

III. SECTION 30(A) DOES NOT PROVIDE PLAINTIFFS WITH AN ENFORCEABLE FEDERAL RIGHT.

Plaintiffs assert that the Eighth Circuit in *Pediatric Specialty III* reaffirmed its earlier holding that section 30(A) grants enforceable rights to Medicaid recipients and providers. Pl. Resp. Mem. p. 15. They state that the United States Supreme Court in vacating *Pediatric Specialty* did not vacate that opinion's §30(A) decision. *Id.* That statement is clearly without basis. The Eighth Circuit's vacated opinion discussed two issues, qualified immunity for two Arkansas state officials and sovereign immunity for the Arkansas human services department. *Pediatric Specialty Care, Inc. v. Arkansas Dep't of Human Servs.*, 443 F.3d 1005, 1012-1013 and 1016-17 (8th Cir. 2006), *vacated as to former sub nom. Selig v. Pediatric Specialty Care, Inc.*, 551 U.S. 1142 (2007). The qualified immunity issue is the part of *Pediatric Specialty* that was vacated and ordered to be dismissed. That issue included the question of whether §30(A) created a federal equal access right. See *id.* at 1013 (stating "We must first consider whether the Medicaid Act confers any federally enforceable rights upon the plaintiffs. . . . The claims for damages made by the plaintiffs here relate only to two subsections of the Medicaid Act: 42 U.S.C. §1396d(a)(13) (Count Four of the Complaint), and 42 U.S.C. §1396a(a)(30)(A) (Count Three of the Complaint.").

With the vacation of the qualified immunity analysis, the Supreme Court left the Eighth Circuit with only a 1993 -- i.e, pre-*Gonzaga* -- opinion as precedent for §30(A) to be enforceable through a §1983 action: *Arkansas Medical Society, Inc. v. Reynolds*, 6 F.3d 519 (8th Cir. 1993). Defendants acknowledge that *Reynolds* held that §30(A) created a federal right. Defs. Mem. in Supp. of J. on the Pldgs 11. Defendants nevertheless contend that *Reynolds* should be reconsidered in light of *Gonzaga*'s higher standards. *Id.* at 11-14. Defendants do understand that the Court may believe that it is without the authority to depart from *Reynolds*' holding despite the very clear movement away from that holding by all five of the circuit courts of appeal that have considered §30(A)'s status post *Gonzaga*. *See id.* at 13-14.

In light of the above, Defendants request that the Court certify for interlocutory appeal the question of whether §30(A) creates federal rights enforceable by Medicaid providers and recipients. 28 U.S.C. §1292(b).⁴ Under §1292(b) there are three criteria for certification: “(1) the order involves a controlling question of law; (2) there is substantial ground for difference of opinion; and (3) certification will materially advance the ultimate termination of the litigation.” *White v. Nix*, 43 F.3d 374, 377 (8th Cir. 1994) (quotation omitted). Here, whether §30(A) creates an enforceable federal right is

⁴ 28 U.S.C. §1292(b) provides, in relevant part, that:

When a district judge, in making in a civil action an order not otherwise appealable under this section, shall be of the opinion that such order involves a controlling question of law as to which there is substantial ground for difference of opinion and that an immediate appeal from the order may materially advance the ultimate termination of the litigation, he shall so state in writing in such order.”

certainly a controlling question of law. There is also substantial ground for a difference of opinion. All circuits that have addressed that question after *Gonzaga* rejected the Eighth Circuit's pre-*Gonzaga* holding in *Reynolds*. Certification will materially advance the termination of the litigation by determining whether Plaintiffs can proceed under §1983. Moreover, certification will allow for greater efficiency in the use of judicial resources in the event that Plaintiffs' motion for a preliminary injunction is denied and Plaintiffs appeal.

IV. PLAINTIFFS' CLAIMS AGAINST THE DEPARTMENT OF HUMAN SERVICES AND THEIR STATE LAW CLAIMS SHOULD BE DISMISSED.

Plaintiffs concede that the Department of Human Services can be dismissed as a Defendant. Pl. Resp. Mem. p. 11 n. 2. Moreover Plaintiffs have not asserted in their Memorandum that the court can retain jurisdiction over their state law claims. They appear to concede that their claims based on state law should be dismissed. As a result, the court should dismiss all claims against the State Agency and all state law claims against the remaining Defendants.

CONCLUSION

Defendants respectfully ask that the Court grant their motion for judgment on the pleadings and dismiss Plaintiffs' Complaint. If however, the Court finds that Plaintiffs have standing, Defendants ask that the Court certify for interlocutory appeal the question of whether Section 30(A) grants Plaintiffs' enforceable federal rights.

Dated: December 7, 2009.

Respectfully submitted,

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